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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,075	07/18/2003	Subhashis Banerjee	BPI-192	3576

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EXAMINER	
BLANCHARD, DAVID J	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/623,075	BANERJEE ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 4-5 and 8 have been amended.

2. Claims 12-13 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 1-11 are under consideration to the extent that the anemia is anemia related to rheumatoid arthritis, i.e., Applicants' elected species.

Objections/Rejections Withdrawn

4. The objection to the specification in the use of various trademarks is withdrawn ni view of applicants' arguments.

5. The objection to claims 1-11 as being drawn to nonelected inventions is withdrawn upon further consideration.

6. The objection to claim 4 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of applicants' arguments.

7. The rejection of claims 4, and 8-11 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of applicants' arguments, i.e., D2E7 is also known as HUMIRA® and adalimumab and is readily available to the public or commercially available.

8. The provisional rejection of claims 1-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/622,205; claims 1-27 of copending Application No. 10/622,210; claims 1-26 of copending Application No. 10/622,683; claims 1-24 of copending Application No. 10/622,928; claims 1-24 of copending Application No. 10/623,065; claims 1-16 of copending Application No. 10/623,035; claims 1-34 of copending Application No. 10/623,076 in view of Salfeld et al [a] (WO 97/29131,

publication date 8/14/1997) is withdrawn in view of the abandonment of the copending applications.

Objections/Rejections Maintained

9. The objection to the specification as disclosing various non-provisional US Application numbers whose status has changed and require updating is maintained.

The response filed 2/20/2007 states that Applicants have reviewed and to the best of Applicants' knowledge the status of the disclosed non-provisional applications are up to date. This has been fully considered but is not found persuasive. USSN 10302,356 at pg. 1, line 14, pg. 6, lines 15 and 30 and pg. 7, line 27 needs to be updated as "now abandoned". Similarly, USSN 10/133,715 at pg. 1, line 15 should be updated as "now abandoned". Additionally, Applicant should update the status of the US Application numbers in the second paragraph beginning at pg. 1, line 17 (e.g., see amendment filed 4/19/2004) given that many of the disclosed applications are "now abandoned". It is noted that USSN 09/801,185 has been allowed and should be updated with the corresponding US Patent number during the pendency of the present application. Applicants' cooperation is again requested in reviewing the entire disclosure for additional non-provisional U.S. Application Numbers that require updating.

Appropriate correction is required.

10. The objection to the title of the invention as not descriptive or clearly indicative of the invention to which the claims are directed is maintained.

The response filed 2/20/2007 requests that this objection be held in abeyance until final disposition and allowance of the claims. This has been fully considered buit is not found persuasive. The claims in the present application are not in condition for allowance and the objection is maintained. Applicant should restrict the title to the treatment of anemia related to rheumatoid arthritis using human TNFα antibodies.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. The rejection of claim 2 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a subject suffering from anemia (*and not pain or neuropathic pain*) in a subject comprising administering a human anti-human TNFα antibody or antigen-binding fragment thereof comprising a light chain comprising CDR1 of SEQ ID NO:7, CDR2 of SEQ ID NO:5 and CDR3 of SEQ ID NO:3 comprising the recited amino acid substitutions and a heavy chain comprising CDR1 of SEQ ID NO:8, CDR2 of SEQ ID NO:6 and CDR3 of SEQ ID NO:4 comprising the recited amino acid substitutions, does not reasonably provide enablement for a method of treating anemia (*and not pain or neuropathic pain*) in a subject comprising administering a human anti-human TNFα antibody or antigen-binding fragment thereof comprising a light chain comprising CDR3 of SEQ ID NO:3 comprising the recited amino acid substitutions and a heavy chain comprising a heavy chain comprising CDR3 of SEQ ID NO:4 comprising the recited amino acid substitutions as broadly encompassed by the claims is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The response filed 2/20/2007 argues that in the method of claim 2, the human antibody or antigen-binding fragment thereof must not only have specific heavy and light chain CDR3 sequences, but must also dissociate from human TNFα with a K_{off} of 1 x 10^{-3} s^{-1} or less, as determined by surface plasmon resonance. Applicant cites MPEP 2164.06, which indicates that the quantity of experimentation is only one factor involved in determining whether "undue experimentation" is required and a considerable amount of experimentation is permissible. Applicant also cites MPEP 2164.08(b), which states that the presence of inoperative embodiments within the scope of a claim does not

necessarily render a claim nonenabled. Applicant refers to pp. 14-19 of the specification which teaches that the heavy and light chain CDR3 domains play an important role in the binding specificity/affinity of an antibody for an antigen and that the CDR3 domains of the light and heavy chain sequences of antibody D2E7 have advantageous properties for use in the invention. Applicants' arguments have been fully considered but are not found persuasive. The scope of the claims remains extremely broad, encompassing human antibodies and antigen-binding fragments thereof that only comprise the CDR3 domains from human anti-TNFα antibody D2E7. For example, the claims encompass human antibodies and antigen-binding fragments thereof that comprise a heavy chain CDR1 from a human antibody that binds HER2, a heavy chain CDR2 from a human antibody that binds EPO, a light chain CDR1 from a human antibody that binds EGFR, and a light chain CDR2 from a human antibody that binds CD30 in combination with the recited D2E7 CDR3 domains, wherein the antibodies dissociate from human TNFα with a K_{off} of 1×10^{-3} s^{-1} or less, as determined by surface plasmon resonance. Again, the teachings and exemplification provided in the specification are limited to human anti-human TNFα antibodies and antigen-binding fragments thereof that comprise all six CDRs, three from the heavy chain and three from the light chain of human anti-human TNFα antibody D2E7, which does not provide adequate guidance and direction to assist those skilled in the art in making and using the broader genus of human antibodies and antigen-binding fragments thereof that only comprise the CDR3 domains of D2E7 and which dissociate from human TNFα with a K_{off} of 1×10^{-3} s^{-1} or less, as determined by surface plasmon resonance. The argument as essentially set forth indicates no disclosure of the genus is necessary, no guidance to make the human antibodies and antigen-binding fragments is required because the skilled artisan can make and test using art recognized techniques to discover how best to practice the claimed invention. This is not persuasive because the issue is make and use, not make and test to see if the skilled artisan could use. The specification does not enable the genus because where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In*

re Soll, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one particular species, what other species will work. See MPEP 2164.03. The art also points out that changing the complementary determining regions is a hit and miss proposition and even minor changes in the amino acid sequences of heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidence by Rudikoff et al (Proc. Natl. Acad. Sci. USA, 79:1979-1983, 1982; of record). Rudikoff et al teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma antibody resulted in the loss of antigen-binding function. Finally, it was well established in the art that the CDRs have a particular order, particular length and that the formation of an intact antigen-binding site of most antibodies routinely requires the association of the complete heavy and light chain variable regions of an antibody each of which consists of three CDRs or hypervariable regions presented in a specific order, which provide the majority of the contact residues for the binding of the antibody to its target epitope Paul ed. Fundamental Immunology, 3rd Edition, 1993, pp 292-295, of record).

Applicants' arguments regarding the fact that not all of the CDRs of an antigen binding site may be necessary in binding a specific antigen and the significance of the CDR3 domains of antibody D2E7 are acknowledged, however, all of the antibody fragments with which applicant argues with the exception of an isolated CDR and a dAb fragment, which consists of the VH domain comprise all of the heavy and light chain CDRs of an antibody in their proper order and in the context of framework sequences which maintain their correct spatial orientation and have the requisite antigen binding function. There is insufficient description and evidence that an antigen-binding fragment which only comprises the CDR3 domains of antibody D2E7 binds human TNFα with a

K_{off} of 1 x 10^{-3} s^{-1} or less, as determined by surface plasmon resonance. Further, while there are some publications, which acknowledge that CDR3 is important, the conformations of other CDRs as well as framework residues influence binding. MacCallum et al (J. Mol. Biol., 262, 732-745, 1996) analyzed many different antibodies for interactions with antigen and state that although CDR3 of the heavy and light chain dominate, a number of residues outside the standard CDR definitions make antigen contacts (see page 733, right col.) and non-contacting residues within the CDRs coincide with residues as important in defining canonical backbone conformations (see page 735, left col.). The fact that not just one CDR is essential for antigen binding or maintaining the conformation of the antigen binding site, is underscored by Casset et al (Biochemical and Biophysical Research Communications, 307:198-205, 2003), which constructed a peptide mimetic of an anti-CD4 monoclonal antibody binding site by rational design and the peptide was designed with 27 residues formed by residues from 5 CDRs (see entire document). Casset et al also states that although CDR H3 is at the center of most if not all antigen interactions, clearly other CDRs play an important role in the recognition process (page 199, left col.) and this is demonstrated in this work by using all CDRs except L2 and additionally using a framework residue located just before the H3 (see page 202, left col.). The issue remains the description of the claimed human antibody variants and guidance and direction of the specification for the claimed variants encompassing just any CDR1 and CDR2 domains in combination with the CDR3 domains of human antibody D2E7. The issue is not make and test, it is not the art that must provide the description to enable the genus of human antibodies and antigen-binding fragments thereof, but Applicants.

The examiner acknowledges applicants remarks regarding US Patent No. 6,090,382, however, applicant is reminded that each US Patent application is examined on its own merits and the examiner is precluded from commenting on an issued patent.

In view of the lack of the predictability of the art to which the invention pertains as evidenced by Paul W. E., Rudikoff et al, MacCallum et al and Casset et al, the lack of guidance and direction provided by applicant, and the absence of working examples, undue experimentation would be required to practice the claimed human antibody

variants that bind human TNFα with a K_{off} of 1 x 10^{-3} s^{-1} or less, as determined by surface plasmon resonance for the treatment of anemia in a subject, with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed human antibodies and absent working examples providing evidence which is reasonably predictive that the claimed human antibody variants bind human TNFα with a K_{off} of 1 x 10^{-3} s^{-1} or less, as determined by surface plasmon resonance, commensurate in scope with the claimed invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. The rejection of claims 1-11 under 35 U.S.C. 102(b) as being anticipated by Salfeld et al [a] (WO 97/29131, publication date 8/14/1997) is maintained.

The response filed 2/20/2007 argues that anemia is a separate and distinct disorder from anemia associated with rheumatoid arthritis as in the prior art. According to applicant, if a patient with rheumatoid arthritis already presents with anemia, it does not necessarily follow that anemia will be treated, just because rheumatoid arthritis is treated. Applicant also states that this is further evidenced by the fact that, each indication for which the drug may be promoted requires separate regulatory approval. Applicants' arguments have been fully considered but are not found persuasive. Applicant's arguments are curious in view of applicants' species election in which

applicant elected anemia associated with rheumatoid arthritis to the extent that the claims are currently under consideration. Thus, applicants argument that anemia is a separate and distinct disorder from rheumatoid arthritis is not found persuasive because the claims are being examined to the extent of the elected species, i.e., "anemia associated with rheumatoid arthritis". Hence, the administration of the human anti-human TNFα antibodies for the treatment of rheumatoid arthritis as taught by Salfeld et al [a] would necessarily treat anemia related to rheumatoid arthritis, which is a common complication of rheumatoid arthritis as evidenced by http://www.emedicinehealth.com/rheumatoid_arthritis/article_em.htm (see middle of pg. 3). Anemia is a common condition noted in patients with rheumatoid arthritis, thus, the anemia cannot be corrected until the inflammatory changes associated with rheumatoid arthritis are controlled with appropriate treatment, i.e., until the administration of anti-TNFα antibodies. Applicants arguments that each indication for which a drug may be promoted requires separate regulatory approval is not found persuasive because FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Scott [v. Finney], 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 [(Fed.Cir. 1994)]. That is, the standards for obtaining a US Patent within the meaning of the patent laws is not coterminus with the standards for obtaining regulatory approval.

Thus, the rejection of claims 1-11 under 35 U.S.C. 102(b) as being anticipated by Salfeld et al [a] is maintained.

15. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Salfeld et al [b] (US Patent 6,509,015 B1, 2/9/1996, IDS reference A3 filed 4/19/2004) is maintained.

The response filed 2/20/2007 states that for the reasons set forth above (i.e., Salfeld et al [a]), Salfeld et al [b] does not teach the claimed methods of the invention. This has been fully considered but is not found persuasive. The examiners remarks

above as applied to Salfeld et al [a] apply here as well and are incorporated herein by reference.

Thus, the rejection of claims 1-11 under 35 U.S.C. 102(e as being anticipated by Salfeld et al [b] is maintained.

16. Claims 1 and 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kempeni J (Ann. Rheum. Dis., 58(Suppl I):I70-I72, 1999) as evidenced by the specification.

The response filed 2/20/2007 states that for the reasons set forth above (i.e., Salfeld et al [a]), Kempeni J does not teach the claimed methods of the invention. This has been fully considered but is not found persuasive. The examiners remarks above as applied to Salfeld et al [a] apply here as well and are incorporated herein by reference.

Thus, the rejection of claims 1-11 under 35 U.S.C. 102(e as being anticipated by Kempeni J is maintained.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. The rejection of claims 1-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 49 of U.S. Patent No. 6,509,015 B1 is maintained.

The response filed 2/20/2007 argues that as stated on pg. 13 of the response against the art of Salfeld et al [b] (US Patent 6,509,015 B1), the cited reference does not teach or suggest the claimed methods of the invention. Applicants' arguments have been fully considered but are not found persuasive. Applicant is reminded that a double patenting rejection is based on the claimed subject matter, not what the conflicting application or patent teaches or suggests. It is reiterated that claims 17 and 49 of U.S. Patent No. 6,509,015 B1 are drawn to a method of inhibiting human TNFα activity in a human subject suffering from rheumatoid arthritis and treating a human subject suffering from rheumatoid arthritis in which TNFα activity is detrimental comprising administering to the human subject a human anti-human TNFα antibody or antigen-binding fragment thereof that is identical to the neutralizing, high affinity human anti-human TNFα antibodies and antigen-binding fragments thereof of the present claims, i.e., identical structures/sequences, binding kinetics and neutralization properties. Thus, the administration of the human anti-human TNFα antibodies and antigen-binding fragments thereof for the treatment of rheumatoid arthritis would necessarily treat anemia related to rheumatoid arthritis. Thus, claims 17 and 49 of U.S. Patent No. 6,509,015 B1 read upon the instantly claimed method and as such are drawn to an invention not patentably distinct from the invention of the present application.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,509,015 B1, discussed above, would form the basis for a rejection of the noted claims under 35

U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

19. The provisional rejection of claims 1-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-8 and 10-15 of copending Application No. 11/435,844 is maintained.

The response filed 2/20/2007 argues that the claims in copending Application No. 11/435,844 are drawn to a method of treating polyarthritis with anti-TNFα antibodies and anemia is a separate and distinct disorder. Anemia can develop as a result of another disease such as chronic infections and inflammatory disease and although the primary disease may be treated with a particular therapeutic agent, there is no expectation that the same therapeutic agent will be efficacious in the treatment of anemia associated with that primary disease. Applicants' arguments have been fully considered but are not found persuasive. Again, applicant is reminded that in view of applicants' species election, i.e., anemia related to rheumatoid arthritis, applicants' arguments that anemia is separate and distinct disorder are not found persuasive. Anemia is a common condition noted in patients with arthritis, thus, the anemia cannot be corrected until the inflammatory changes associated with the arthritis are controlled with appropriate treatment, i.e., administration of anti-TNFα antibodies. Thus, claims claims 1, 4-8 and 10-15 of copending Application No. 11/435,844 read upon the

instantly claimed method and as such are drawn to an invention not patentably distinct from the invention of the present application.

Applicant is reminded that he U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/435,844, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

20. The provisional rejection of claims 1-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23, 58, 60-70 and 73-84 of copending Application No. 10/163,657 in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997) is maintained.

The response filed 2/20/2007 argues that the claims in copending Application No. 10/163,657 are drawn to a method of treating rheumatoid arthritis with anti-TNFα antibodies, however, anemia is a separate and distinct disorder and anemia can develop as a result of another disease such as chronic infections and inflammatory disease and although the primary disease may be treated with a particular therapeutic agent, there is no expectation that the same therapeutic agent will be efficacious in the treatment of anemia associated with that primary disease. Applicants' arguments have been fully considered but are not found persuasive. Applicant is reminded that in view

of applicants' species election, i.e., anemia related to rheumatoid arthritis, applicants' arguments that anemia is separate and distinct disorder are not found persuasive. Anemia is a common condition noted in patients with rheumatoid arthritis, thus, the anemia cannot be corrected until the inflammatory changes associated with rheumatoid arthritis are controlled with appropriate treatment, i.e., until the administration of anti-TNFα antibodies. Thus, claims 1-23, 58, 60-70 and 73-84 of copending Application No. 10/163,657 in view of Salfeld et al [a] read upon the instantly claimed method and as such are drawn to an invention not patentably distinct from the invention of the present application.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/163,657, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. The provisional rejection of claims 1-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-19 of copending Application No. 11/233,252 in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997) is maintained.

The response filed 2/20/2007 argues that the claims in copending Application No. 11/233,252 are drawn to a method of treating rheumatoid arthritis and other diseases, but not anemia with anti-TNFα antibodies. Anemia is a separate and distinct disorder, which can develop as a result of another disease such as chronic infections and inflammatory disease and although the primary disease may be treated with a particular therapeutic agent, there is no expectation that the same therapeutic agent will be efficacious in the treatment of anemia associated with that primary disease. Applicants' arguments have been fully considered but are not found persuasive. Applicant is reminded that in view of applicants' species election, i.e., anemia related to rheumatoid arthritis, applicants' arguments that anemia is separate and distinct disorder are not found persuasive. Anemia is a common condition noted in patients with rheumatoid arthritis, thus, the anemia cannot be corrected until the inflammatory changes associated with rheumatoid arthritis are controlled with appropriate treatment, i.e., administration of anti-TNFα antibodies. Thus, claims 15-19 of copending Application No. 11/233,252 in view of Salfeld et al [a] read upon the instantly claimed method and as such are drawn to an invention not patentably distinct from the invention of the present application.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/233,252, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon

the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

22. The provisional rejection of claims 1-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/622,932; claims 1-23 of copending Application No. 10/623,039; claims 1-16 of copending Application No. 10/623,318 in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997) is maintained.

The response filed 2/20/2007 argues that none of the claims in the above copending applications are drawn to a method of treating a patient with anemia and anemia is a separate and distinct disorder from that claimed in the above copending applications. Applicant argues that anemia can develop as a result of another disease such as chronic infections and inflammatory disease and although the primary disease may be treated with a particular therapeutic agent, there is no expectation that the same therapeutic agent will be efficacious in the treatment of anemia associated with that primary disease. Applicants' arguments have been fully considered but are not found persuasive. Applicant is reminded that in view of applicants' species election, i.e., anemia related to rheumatoid arthritis, applicants' arguments that anemia is separate and distinct disorder are not found persuasive. Anemia is a common condition noted in patients with rheumatoid arthritis, thus, the anemia cannot be corrected until the inflammatory changes associated with rheumatoid arthritis are controlled with appropriate treatment, i.e., administration of anti-TNFα antibodies. Thus, claims 1-14 of copending Application No. 10/622,932; claims 1-23 of copending Application No. 10/623,039; claims 1-16 of copending Application No. 10/623,318 in view of Salfeld et al [a] read upon the instantly claimed method and as such are drawn to an invention not patentably distinct from the invention of the present application.

23. No claims are allowed.

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

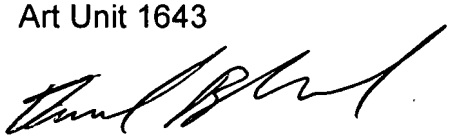
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Blanchard
Primary Examiner
Art Unit 1643



DB
May 8, 2007